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September 9, 1996

**VIA HAND DELIVERY**

The Hon. Donna E. Shalala

Secretary

Department of Health and Human Services

Sixth Floor

200 Independence Avenue, S.W.

Washington, D.C. 20201

Re: Fulfillment of Reporting Obligation  
under 21 U.S.C. § 343(r)

Dear Secretary Shalala:

Coastside Bio Resources, by counsel and in accordance with the requirements of 21 U.S.C. § 343(r), hereby reports its statements of nutritional support. Under that section, companies are not only required to make such a reporting but also to retain substantiation for each such statement. In proof of its compliance with that additional requirement, Coastside Bio Resources herein submits citations to some, but not all, of the scientific documentation it retains in support of the statements. In accordance with the requirements of Section 343(r), Coastside Bio Resources includes the following disclaimer in boldface type, prominently displayed upon each piece of literature that bears any statement listed below: **This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

**Product**

Sea Cucumber

**Statement**

For generations the Chinese have called on the lowly sea cucumber to provide nutritional support for proper joint functioning.

Maintenance of healthy joints, support for connective tissue,

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and protection of healthy cartilage have been their objectives.

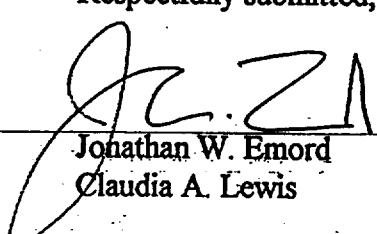
Sea Cucumber contains mucopolysaccharides, including a high percentage of chondroitin sulfates, which are important elements of human cartilage.

Maine Sea Cucumber's objectives are: (1) to provide a nutritional support to the body's cells which help rebuild and maintain cartilage, and (2) to promote comfortable joint function.

**Representative Sampling of Supportive Data:**

V. Rejholey, "Long-Term Studies of Antiostearthritic Drugs An Assessment," 17 *Seminars in Arthritis and Rheumatism*, 35-53 (1987); V.R. Pipitone, "Chondroprotection with Chondroitin Sulfate," 17 *Drugs Exptl. Clinial Res.* 3-7 (1991); and A. Baici and P. Bradamante, "Interaction between Human Leuteocyte Elastase and Chrondroitin Sulfate," 51 *Chem. - Biol. Interactions* 1-11 (1984).

Respectfully submitted,



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Claudia A. Lewis